REMARKS

The present amendment is in response to the Office Action dated 1 July 2009, where the Examiner has rejected claims 34-51. Applicants thank the Examiner for the thorough review of the application as demonstrated by the Office Action. In the present amendment, claims 34-51 have been amended. Support for the amendments can be found throughout the specification. Reconsideration and allowance of pending claims 34-51 in view of the amendments and the following remarks are respectfully requested.

A. 35 USC §112, first paragraph

The Office Action rejects Claims 34-51 for lack of written description pursuant to 35 U.S.C. §112, first paragraph. In particular, the Office Action asserts that there is inadequate written description of using a fluid other than a liquid as the first phase.

Applicants have amended independent Claim 34 to recite, *inter alia*, "a material for the first phase in a fluid state, wherein the material is selected from a liquid, or a solid in powder, grain or granule form, or a plastic solid, such that it is able to flow." Thus, Claim 34 no longer recites that the first phase can be a gas. Accordingly, to the extent that the written description rejection results from claiming a gas as the first phase, the rejection is rendered moot.

Meanwhile, Applicants respectfully submit that there is adequate written description for the first phase being a solid in the form of a powder or granules. The specification states:

> Preferably, the first phase is not in a liquid or wholly liquefied state but is, or is rendered sufficiently fluid to mix with and to carry or coat the second phase .... both the first phase and the second phase may be in particulate or powder form.

Specification (published as WO/2004/084968) at pg. 2, lines 24-29.

Consequently, the Specification clearly conveys that the inventors contemplated solid powder or granules could be used as the first phase in the claimed invention. Therefore, the Specification provides adequate written description for Claim 34-51.

For at the least the reasons stated above, Claims 34-51 have adequate written description. Withdrawal of the rejection is respectfully requested.

B. 35 USC §112, second paragraph

The Office Action rejects various claims as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Without acquiescing to the rejections of independent Claim 34, but in order to expedite prosecution, Applicants have amended Claim 34 to correct various deficiencies that are alleged in the Office Action. Applicants believe amended Claim 34 is clear and definite, and overcomes the present indefiniteness rejections.

With regards to the rejection of Claims 38-41, Applicants respectfully disagree with the rejection. The Office Action states that the claims are unclear because both phases can be the same polymer, which would result in only a single phase. Nevertheless, Applicants submit the claimed composition could consist of a single polymer, and still have two phases.

The Specification contemplates that "[t]he first and second phases used in the invention may be made from similar materials, with different solidifying or setting properties." Specification at pg. 4, lines 1-2. Thus, for example, the same type of polymer may be used for each phase, but due differences in molecular weight, the solidifying properties may vary. Other non-limiting examples how different phases may result from the same polymer include differences in the cross-linking, crystallinity, copolymer form (*e.g.*, block or random copolymer), porosity, etc. Accordingly, Claims 38-41 are not inconsistent with a composition having two phases, and are therefore clear and definite.

For at least the reasons stated above, Claims 34-51 are clear and definite. Withdrawal of the rejection is respectfully requested.

C. 35 USC §103(a)

Claims 34-51 stand rejected under section 103(a) as being unpatentable over U.S. Patent No. 6,841,617 ("Jeong") in view of U.S. Patent No. 6,290,729 ("Slepian"), and if necessary in further view of U.S. Patent No. 6,818,018 ("Sawhney") or U.S. Patent No. 6,129,761 ("Hubbell"). As set forth in MPEP § 2143, in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 127 S. Ct. 1727, 82 USPQ2d 1385, 1395-97 (2007) the Supreme Court identified a number of rationales to support a conclusion of obviousness which are consistent with the proper "functional approach" to the determination of obviousness as laid down in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The KSR Court noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit.

Jeong relates to a biodegradable gelling liquid having utility as a drug delivery system. The drug delivery system is parenterally injectable, releases drugs at a desired rate, and biodegrades at a desired rate. See Jeong, col. 3, lines 20-67. Jeong contains no disclosure or suggestion of a material for a second phase contained within the gelling liquid.

Furthermore, there is a limit on the molecular weight of polyester that can be used in Jeong (maximum MW 100,000) due to solubility limits. The present claimed invention does not have this restriction. Higher molecular weights offer improved mechanical strength and longer degradation times. The present claimed invention can achieve mechanical strengths much greater than those possible with gel systems such as Jeong. This is useful in certain sites where compressive resistance is needed.

Applicants assert that there is simply no motivation for a second material to be dispersed within Jeong's gelling liquid, except to reconstruct Applicants' claimed invention. Applicants remind the Examiner that the use of hindsight in rejecting claims is not permitted.

Furthermore, all of the cited references relate to hydrogels or organogels. The nature of these substantially liquid materials means that they are not able to obtain macroporosity as in the claimed invention. As discussed at page 9, penultimate paragraph, of the Specification, the porous structure is formed by gaps between particles, or by the incomplete liquefaction of the first phase, in addition to the inherent porosity of the particles themselves.

None of the cited references disclose or suggest the use of a composition where a second material is distributed through a first material, where the first material can be solidified, in situ in a tissue material, such that a porous matrix is formed. None of the cited references even contemplate the significance of porosity.

None of the cited references' products are solidifiable to form a porous matrix, the matrix comprising a first phase and a second phase contained within the first phase, as required by the present Claims.

Turning now to Slepian specifically, Slepian mentions permeability, but this is a much smaller scale than having actual pores in a matrix structure (macropores). Indeed, the product of Slepian can be used as a sealant to exclude cell or protein transfer. This use as a sealant would undermine Applicants' teachings of forming a porous matrix, and therefore undermine independent Claim 34, for example. Thus, Slepian teaches away from having a porous structure, as recited in the Claims.

As should be understood, the provision of a composition that can be solidified to form a porous matrix is particularly beneficial. This means that diffusion can occur through the formed matrix, which can be used as a tissue scaffold. Further, the matrix can be loaded with cells.

Specifically, this porosity is needed for nutrient transfer and to provide space for cells to proliferate or form tissue structures. It can, for example, be highly beneficial to encourage local endogenous cells to grow within the porous matrix when used as a tissue scaffold.

It is further noted that an advantage of the claimed invention is that it can have an open pore structure, e.g. interconnected pores connecting the center to the surface. This is inherently achieved when pores are formed between co-attached particles.

Also, in the gel systems of the cited references, water must be present. If it is desired to add growth factors, drugs etc, these are contacted by the water component of the gel. However, they may be labile under these conditions. In the present invention there is no requirement for water to be present and therefore added components such as growth factors and drugs can be included without any concern.

In summary, there is nothing in Jeong that teaches the skilled artisan that he should produce a tissue scaffold wherein the matrix of the scaffold is two-phase and additionally is porous. Furthermore, Slepian teaches away from having a porous structure, as recited in the claims. The balance of cited references do not overcome the deficiencies of Jeong and Slepian.

Neither Jeong nor Slepian provides the skilled artisan with any teaching towards a beneficial tissue scaffold product in accordance with the invention, which has the advantage of being able to be created from a solidifiable matrix in a single step. Accordingly, Applicants assert that Claims 34-51 are presently in condition for allowance and a notice of allowance including Claims 34-51 is respectfully requested.

CONCLUSION

For all the foregoing reasons, early allowance of pending Claims 34-51 is respectfully requested. If the Examiner believes that a telephone conversation may be useful in advancing prosecution, the Examiner is invited to contact the undersigned at the number listed below. If necessary, applicant requests to extend the period for filing this reply pursuant to 37 CFR 1.136(a) and authorizes the Director to charge any additional fee(s) or any underpayment of fee(s) or credit any overpayment(s) to Procopio Deposit Account No. 50-2075.

Respectfully submitted,

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